K951967

Summary of Safety and Effectiveness
Cardiometrics Doppler Guide Wires
Report of Device Modification
510(k) Modification K 951567

OCT 25 1996

Trade Name: Cardiometrics FloWire Doppler Guide Wire and SmartWire Doppler Guide Wire

Generic Name: Doppler Guide Wire

Manufacturer: Cardiometrics, Inc.
645 Clyde Avenue
Mountain View, California 94043
Establishment Registration Number: 2938946

Classification:
In preparation of this PreMarket Notification, it was determined that devices of this generic type have been previously classified as Class II devices. No performance standards have yet been established for these products.

Product Description:
This 510(k) Notification is being submitted for modifications to the tip mounted transducer of Cardiometrics Doppler Guide Wires (both FloWire and SmartWire Doppler Guide Wires). The transducer modifications allow the beam width to increase from 28° to 35° and allow the Doppler Guide Wires to all function at 12 MHz. Previously, the .014" Doppler Guide Wire functioned at 15 MHz and the .018" Doppler Guide Wire functioned at 12 MHz. This modified transducer will be more efficient with a higher signal to noise ratio which with the wider beam width will allow for easier signal acquisition by the user when positioning the Doppler Guide Wire in the vessel.

The currently marketed FloWire and SmartWire Doppler Guide Wires have the mechanical properties of other floppy steerable guide wires with the addition of a tip mounted ultrasound Doppler transducer. FloWire and SmartWire Doppler Guide Wires connect to a Rotary Connector Cable which is supplied with each guide wire. The Rotary Connector Cable in turn connects to the Patient Cable which connects to the Cardiometrics FloMap Ultrasound Instrument. The FloMap Instrument incorporates the electronics and software required to process the Doppler ultrasound signals in real time, displaying blood flow velocity measurements and spectral patterns on the instrument monitor. Blood flow velocity measurements are obtained using the FloWire and SmartWire Doppler Guide Wires to provide hemodynamic information in diagnostic and/or interventional procedures.

Intended Use:

The FloWire Doppler Guide Wires and the FloMap Ultrasound Instrument measure blood velocities in peripheral and coronary arteries. The FloWire/FloMap System are intended for use in conjunction with diagnostic procedures such as peripheral and coronary angiography and for interventional procedures such as balloon angioplasty, as well as other interventional procedures which utilize a guide wire in the peripheral and coronary vasculature. The SmartWire Doppler Guide Wire and SmartMap Ultrasound Instrument are intended for use in the cerebral vasculature to measure blood flow velocities during diagnostic angiography and/or any interventional procedures.

Rationale for Substantial Equivalence:

Cardiometrics Doppler Guide Wires (FloWire and SmartWire Doppler Guide Wires) are devices which were found to be substantially equivalent to predicate devices. Cardiometrics Doppler Guide Wires with the modified transducer are substantially equivalent to currently marketed Cardiometrics Doppler Guide Wires with regard to intended use, materials, and design.

This modified transducer allows for a more efficient transducer with a higher signal to noise ratio and wider beam width. The actual velocities provided by the existing transducer and the modified transducer when adequate signals are received will be identical. The basic overall design, methods of manufacturing, and materials used are substantially equivalent to existing Doppler Guide Wires.

Biocompatibility Evaluations:

Cardiometrics Doppler Guide Wires have been tested and meet the requirements of the USP XXII Class IV testing for plastics and the tests outlines in the Tripartite Biocompatibility Guidance for Medical Devices (September 1986). The biocompatibility test results provided support the safety of the subject device. No changes have been made which affect the biocompatibility testing.

Summary:

Based upon the transducer modification described in this summary, the Cardiometrics Doppler Guide Wires with modified transducers are substantially equivalent to those transducers utilized in existing Doppler Guide Wires. The intended use and method of operation remain identical. Also, the methods of construction and materials used are either identical or substantially equivalent to their existing Doppler Guide Wires.